REMARKS/ARGUMENTS

Clams 1-23 are currently pending. Claims 1, 3, 10, 11 and 17 have been examined, and claims 2, 4-9, 12-16, and 18-23 stand withdrawn.

The specification has been amended to recite the cross-reference to priority data on page 1 of the specification. Claim 1 has been amended to recite that the Group B *Streptococcus* protein or polypeptide is "isolated," and further that it comprises "the amino acid sequence of SEQ ID NO: 72." Written support for this amendment may be found in the specification as a whole, for example page 6 line 22. Claims 3, 10 and 17 have been amended for clarification purposes and to eliminate reference to claims which have been withdrawn due to the restriction requirement; these amendments are not for reasons related to patentability.

Applicant respectfully requests entry of the above amendments and submits that the amendments are all fully supported by the specification and do not constitute new matter.

Claim Objections Under 37 C.F.R. 1.821(d)

This disclosure stands objected to because page 1 lacks cross reference to priority data and because sequence identification numbers are missing from sequences recited in the specification.

The specification has been amended to recite the required cross reference on page 1. Applicant respectfully submits that this amendment does not introduce any new matter because Applicant properly claimed priority in compliance with 37 C.F.R. § 1.78, as evidenced by the filing receipt which recites the appropriate claim to priority. As for the missing sequence identifier numbers, Applicant respectfully reminds the Examiner that the appropriate SEQ ID NOs were added to the specification and figures in the Preliminary Amendment filed February 13, 2003. Thus, Applicant submits that the Examiner's objections have been overcome and respectfully requests that the objections be withdrawn.

Claim Rejections Under 35 U.S.C. § 101

Claims 1 and 3 stand rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter because the claims do not recite that the protein is isolated or purified.

Applicants have amended claim 1 to recite "An *isolated* Group B *Streptococcus* protein..." Written support for this amendment may be found in the specification as a whole, for example page 6 line 22. Thus, Applicant submits that the Examiner's rejections have been overcome and respectfully requests that the rejections be withdrawn.

Claim Rejections Under 35 U.S.C. § 112, second paragraph

Claims 1, 3, 10, 11 and 17 stand rejected under 35 U.S.C. § 112, second paragraph as containing non-elected subject matter. Also, claim 3 is rejected because the recitation of "at least 50% identity" is purportedly indefinite.

Applicant has amended the claims to recite the specific sequence of interest from Figure 1, i.e., SEQ ID No: 72 (ID-38). As for claim 3, Applicant respectfully submits that the specification provides adequate support for and explanation of what 50% identity to the proteins or polypeptides of the invention means. *See, e.g.,* Specification at page 4, line 25 to page 6, line 15. Accordingly, Applicant submits that the Examiner's rejections have been overcome and respectfully requests that the rejections be withdrawn.

Claim Rejections Under 35 U.S.C. § 112, first paragraph--enablement

Claims 1, 3, 10, 11 and 17 stand rejected for failing to comply with the enablement requirement. The Examiner alleges that SEQ ID NO: 72 (ID-38) has not been shown or described to have any activity, or to be useful as a vaccine against Group B *Streptococcus* challenge. This rejection is respectfully traversed.

A specification satisfies the enablement requirement if the scope of the claims in question is enabled, so that a person of ordinary skill in the art would be able to make and use the claimed invention without undue experimentation. MPEP 2164. If some experimentation is necessary, it does not preclude enablement, so long as the experimentation is not unduly extensive. MPEP 2164.06. "[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). Furthermore, "[t]he test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the

experimentation should proceed." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicants respectfully submit that the specification provides a substantially broader scope of enablement than is alleged in the Office Action. The specification provides ample guidance for carrying out the experimentation necessary to determine whether sequences within the claims are useful as a vaccine. For instance, the specification describes the nuclease screening system used to identify the novel DNA sequences of the invention (pages 15-22); the preparation of DNA vaccines comprising the novel sequences (pages 22-25); the *in vivo* passaging and intra-peritoneal challenge and virulence testing of Group B *Streptococcus* (pages 25-26); and numerous vaccine trials (pages 26-42).

Indeed, the specification, as acknowledged by the Examiner (Office Action, page 4), provides many examples of how to determine whether Streptococcal polypeptides are useful as a vaccine. Specifically, the specification details vaccination trials with *twenty-five different* DNA sequences obtained in the screening system of the invention, with eight of these sequences (about one-third of those tested) conferring significant resistance to immunized mice against Group B *Streptococcus* challenge. Pages 27-42.

Furthermore, using the method of the invention as detailed in the specification, it has been demonstrated that at least two sequences comprising SEQ ID NO: 72 (ID-38) confer significant resistance to immunized mice against Group B *Streptococcus* challenge. *See* Declaration of Jeremy Wells, submitted herewith. In these experiments, ID-38FL and ID-38TF were shown to provide prophylactic immunization to Group B *Streptococcus* infection as compared to the negative control. ID-38FL is the full-length protein, consisting of 861 amino acids and comprising all 485 amino acids of SEQ ID NO:72. ID-38TF is the truncated variant of ID-38FL, consisting of 516 amino acids and comprising all 485 amino acids of SEQ ID NO:72.

These experiments demonstrate that one of ordinary skill in the art, using the instant specification as guidance, could have routinely determined whether a protein or polypeptide comprising the amino acid sequence of SEQ ID NO: 72 (ID-38) would be useful as a vaccine against Group B *Streptococcus*. Accordingly, Applicants respectfully request that the enablement rejection be withdrawn.

Claim Rejections Under 35 U.S.C. § 112, first paragraph--written description

Claims 1, 3, 10, 11 and 17 stand rejected for failing to comply with the written description requirement. The Examiner alleges that the "specification does not describe ID-38 (SEQ ID NO: 72) or the fragments or variants of ID-38 having any activity." Office Action, page 5. This rejection is respectfully traversed.

The written description requirement requires that the specification give adequate support for claiming the subject matter in question. MPEP 2163.01. The description must allow a person of ordinary skill in the art to recognize what is claimed. MPEP 2163.02. Applicant is claiming proteins and polypeptides comprising the amino acid sequence of SEQ ID NO: 72, or fragments or derivatives thereof. Applicant has disclosed the precise structure of SEQ ID NO: 72. *See* Sequence Listing, pages 52-53. Accordingly, Applicant submits that it has provided adequate support for the "proteins" and "polypeptides" of Claim 1.

As for the Examiner's contention that the specification does not describe "fragments or variants" of SEQ ID NO: 72, Applicant initially points out that the amended claims refer to "*derivatives* or variants." The specification expressly teaches what is meant by derivatives or variants. *See, e.g.,* Specification at page 4, line 10 to page 5, line 26; page 8, lines 5-29; page 9, lines 6-9. For instance, the specification teaches that "derivatives or variants" may include proteins and polypeptides of the invention comprising alterations in the amino acid sequence which do not affect the function of those proteins or polypeptides. *See id.* at page 4, line 10 to page 5, line 26. The specification also teaches that the term "derivatives" encompasses antibody fragments and synthetic constructs, such as those described by Dougall et al. in *Tibtech 12*, 372-379 (September 1994). *See id.* at 8, lines 4-8

Accordingly, Applicant submits that it has provided adequate support for derivatives or variants of the invention, and respectfully requests that the written description rejections be withdrawn.

If after this amendment there are issues remaining which discussion could advance prosecution, Applicants respectfully request that the Examiner call the undersigned attorney at the phone number listed.

Respectfully submitted,

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